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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,679	11/14/2003	Denise Faustman	00786/428002	2917

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EXAMINER	
JUEDES, AMY E	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/713,679	FAUSTMAN, DENISE	
	Examiner	Art Unit	
	Amy E. Juedes, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-55* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-55* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

1-6. Claims 1-2, 4-5, drawn to a method of screening a test compound comprising contacting a blood sample from a first and a second mammal with said compound, wherein groups 1-6 correspond to blood samples comprising leukocytes overexpressing FasL, TNF, IL-1, IL-6, IL-12, or IFN-gamma, respectively; classified in Class 435, subclass 2.

7. Claims 1, 3-5, drawn to a method of screening a test compound comprising contacting a blood sample from a first and a second mammal with said compound, wherein the blood sample comprises leukocytes deficient in CD180; classified in Class 435, subclass 375.

Claims 1 and 4-5 link(s) inventions 1-7. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1 and 4-5. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

8. Claims 6-8, drawn to a method of screening a test compound comprising contacting a blood sample from a first and a second mammal with an inhibitor of apoptosis or an inhibitor of necrosis; classified in Class 435, subclass 412.

9. Claims 9-11, drawn to a method of screening a test compound comprising contacting a population of autoimmune cells from a

mammal, and a second blood element from said mammal with said test compound; classified in Class 435, subclass 355.

10-15. Claims 12-15, 18-20, drawn to a method for diagnosing an autoimmune disease comprising contacting a blood sample from a first and a second mammal with a compound, wherein the compound is TNF-alpha, and wherein groups 10-15 correspond to blood samples comprising leukocytes overexpressing FasL, TNF, IL-1, IL-6, IL-12, or IFN-gamma, respectively; classified in Class 435, subclass 325.

16. Claims 12-14, 16, 18-20, drawn to a method for diagnosing an autoimmune disease comprising contacting a blood sample from a first and a second mammal with a compound, wherein the compound is TNF-alpha, and wherein the blood samples comprises leukocytes overexpressing BCMA; classified in Class 435, subclass 363.

17. Claims 12-14, 17-20, drawn to a method for diagnosing an autoimmune disease comprising contacting a blood sample from a first and a second mammal with a compound, wherein the compound is TNF-alpha, and wherein the blood samples comprises leukocytes deficient in CD180; classified in Class 435, subclass 352.

18-23. Claims 12-15, 18, 20-21, drawn to a method for diagnosing an autoimmune disease comprising contacting a blood sample from a first and a second mammal with a compound, wherein the compound is an antibody agonist of the TNF-alpha receptor, and wherein groups 18-23 correspond to blood samples comprising leukocytes overexpressing FasL, TNF, IL-1, IL-6, IL-12, or IFN-gamma, respectively; classified in Class 435, subclass 366.

24. Claims 12-14, 16, 18, 20-21, drawn to a method for diagnosing an autoimmune disease comprising contacting a blood sample from a first and a second mammal with a compound, wherein the compound is an antibody agonist of the TNF-alpha receptor, and wherein the blood samples comprises leukocytes overexpressing BCMA; classified in Class 435, subclass 372.2.

25. Claims 12-14, 17-18, 20-21, drawn to a method for diagnosing an autoimmune disease comprising contacting a blood sample from a first and a second mammal with a compound, wherein the compound is an antibody agonist of the TNF-alpha

receptor, and wherein the blood samples comprises leukocytes deficient in CD180; classified in Class 435, subclass 372.

26-31. Claims 12-15, 18, 22-23, drawn to a method for diagnosing an autoimmune disease comprising contacting a blood sample from a first and a second mammal with a compound, wherein the compound binds to a Toll-like receptor, and wherein groups 26-31 correspond to blood samples comprising leukocytes overexpressing FasL, TNF, IL-1, IL-6, IL-12, or IFN-gamma, respectively; classified in Class 435, subclass 347.

32. Claims 12-14, 16, 18, 22-23, drawn to a method for diagnosing an autoimmune disease comprising contacting a blood sample from a first and a second mammal with a compound, wherein the compound binds to a Toll-like receptor, and wherein the blood samples comprises leukocytes overexpressing BCMA; classified in Class 435, subclass 372.3.

33. Claims 12-14, 17-18, 22-24, drawn to a method for diagnosing an autoimmune disease comprising contacting a blood sample from a first and a second mammal with a compound, wherein the compound binds to a Toll-like receptor, and wherein the blood samples comprises leukocytes deficient in CD180; classified in Class 435, subclass 366.

Claims 12-14 link(s) inventions 10-33. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 12-14. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

34. Claims 25-32, drawn to a method for diagnosing an autoimmune disease comprising contacting a population of autoimmune cells from a mammal, and a second blood element from said mammal with a compound, wherein the compound is TNF-alpha; classified in Class 435, subclass 372.3.

35. Claims 25-30, 32-33, drawn to a method for diagnosing an autoimmune disease comprising contacting a population of autoimmune cells from a mammal, and a second blood element from said mammal with a compound, wherein the compound is an antibody agonist of the TNF-alpha receptor; classified in Class 435, subclass 372.3.

36. Claims 25-30, 34-36, drawn to a method for diagnosing an autoimmune disease comprising contacting a population of autoimmune cells from a mammal, and a second blood element from said mammal with a compound, wherein the compound binds a Toll-like receptor; classified in Class 435, subclass 372.2.

Claims 25-30 link(s) inventions 34-36. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 25-30. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

37-42. Claims 37-38, 41-47 drawn to a method for stratification of a human patient into a therapeutic subgroup comprising contacting a blood sample from said patient with a compound, wherein groups 37-42 correspond to blood samples comprising leukocytes overexpressing FasL, TNF, IL-1, IL-6, IL-12, or IFN-gamma, respectively; classified in Class 530, subclass 351.

43. Claims 37, 39, 41-47 drawn to a method for stratification of a human patient into a therapeutic subgroup comprising contacting a blood sample from said patient with a compound, wherein the blood samples comprises leukocytes overexpressing BCMA; classified in Class 530, subclass 350.

44. Claims 37, 40-47 drawn to a method for stratification of a human patient into a therapeutic subgroup comprising contacting a blood sample from said patient with a compound, wherein the blood samples comprises leukocytes deficient in CD180; classified in Class 530, subclass 380.

Claims 37 and 41-47 link(s) inventions 37-44. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 37 and 41-47 Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

45. Claims 48-55, drawn to a method monitoring a therapy for a human that has an autoimmune disease comprising contacting a blood sample with a compound; classified in Class 514, subclass 2.

2. Groups 1-45 are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to methods comprising different method steps, different reagents, resulting in different endpoints. For example, the methods require different reagents, such as

different blood samples, different populations of leukocytes, and different compounds. The methods also require different method steps and result in different endpoints (for example, diagnosing disease, screening a test compound, monitoring therapy of established autoimmune disease, etc.).

3. These inventions are distinct for the reasons given above. In addition, they have acquired a separate status in the art as shown by their recognized divergent subject matter. Further, a different field of search would be required based upon the various methods of comprising distinct reagents, method steps, and endpoints. Therefore restriction for examination purposes as indicated is proper.

4. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Amy E. Juedes whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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August 23, 2006

8/27/06
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PRIMARY EXAMINER